

REMARKS UNDER 37 CFR § 1.116

Formal Matters

Claims 9-13, 15-18 and 30-38 were examined and rejected. Claims 1-8, 14 and 19-29 were previously cancelled.

No claim amendments are being made herein. Claims 9-13, 15-18 and 30-38 remain pending in the application.

Rejections Under 35 U.S.C. §103

Claims 9-13, 15-18 and 30-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kuehn et al. (USPN 6,165,183) in view of Cribier et al. (USPN 4,777,951).

Claim 9, as well as claims 10-13, 15-18 and 30-38 by virtue of their dependency on claim 9, are directed to a method of repairing cardiac valves using an apparatus comprising a fastener which is used to both temporarily grasp (step b) and permanently secure (step e) together the leaflets of a cardiac valve. The claimed method is further directed to determining whether to permanently secure valve leaflets at a selected apposition point based upon the measured blood flow and/or the pressure gradient through the valve when the fastener is temporarily grasping the valve's leaflets at the apposition point (step d).

Kuehn et al. do not disclose using an apparatus having a fastener capable of performing both of the claimed functions. While Kuehn et al. discuss "a single element gripper/fastener" instrument (such as the embodiment of Figs. 13A-F), the fasteners are not configured to temporarily grasp the leaflets, i.e., they are not capable of being released from the leaflet once grasped to the leaflet. Instead, the fasteners are meant to be permanently fastened to the leaflets with a single application. With reference to Figs. 13A-F for example, gripper arms 258, 260, once deployed from sleeve 254, cannot be undeployed. Further, Kuehn et al. do not disclose or recognize a need to temporarily grasp the leaflets.

Cribier et al. are cited for their teaching of measuring the pressure gradient across a valve during an aortic valvuloplasty which involves the use of an inflatable balloon to dislodge plaque from the valve leaflets. The balloon is repeatedly inflated and the pressure gradient measured between inflations until the gradient reaches a satisfactory value. Cribier et al. do not teach or

suggest anything about applying fasteners or the like to valve leaflets and measuring across the valve to determine the effectiveness of the fastening site on the leaflet.

Neither Kuehn et al. nor Cribier et al. nor the combination thereof disclose, teach or suggest the claimed method. In particular, they do not disclose, teach or suggest a fastener that is configured to temporarily grasp and to permanently fasten leaflets together, and as such, they do not disclose, teach or suggest the step of determining whether to permanently secure the valve leaflets at a selected apposition point based upon at least one of said measured blood flow and pressure gradient. Such determination would not be contemplated by one practicing the Kuehn et al. devices as those devices cannot allow for the option to subsequently release a fastener once deployed on the leaflet. Accordingly, Applicants respectfully request withdrawal of this rejection and allowance of the claims.

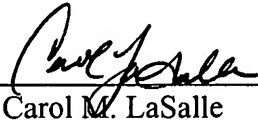
Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CATT-001.

Respectfully submitted,
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Date: 7/2/04

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